K033333

NOV 1 4 2003

SMDA 510(k) SUMMARY

This summary of 510(k) safety and effective information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR Section 807.93.

A. GENERAL INFORMATION

1. Applicant:

Name & Address : Aomori Olympus Optical Co., Ltd
248-1 Okkonoki 2-choume Kuroishi-shi
Aomori, Japan, 036-0367

Registration No. : 9614641

2. Initial Importer:

Name & Address : Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-315

Registration No. : 2429304

3. Submission Correspondent:

Name & Address : Tina Steffanie-Oak
Associate Manager, RA/Clinical Monitor
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-3157

Telephone : 631-844-5477

Facsimile : 631-844-5416

B. DEVICE IDENTIFICATION

1. **Trade Name** : Single Use 3-Lumen Balloon Catheter, B-230Q-A / B-230Q-B
2. **Common Name** : Balloon catheter
3. **Classification Name**: Endoscope and Accessories
4. **CFR Number** : 876.1500
5. **Classification Panel** : 78
6. **Product Code** : FGE, KOG

C. PREDICATE DEVICE INFORMATION

B-5 /B-7 series Balloon Catheter K962925

D. DEVICE DESCRIPTION

The subject device(s) is a balloon catheter that has a triple-lumen catheter and a multiple sizing balloon with pre-measured syringes, to be used in accordance with Intended use of the device.
These functions ensure smoother passage of the guidewire and injection of the contrast media without removing the guidewire, and enable to inflate one balloon to 3 different sizes.

These modifications give operational assistance to save time for physicians, or minimize the inventory. The operation is basically identical with the predicate device. We believe that these modifications would not affect safety and effectiveness.

E. INTENDED USE OF THE DEVICE

The subject devices, Single Use 3-Lumen Balloon Catheter B-230Q-A/ B-230Q-B have been designed to be used with an Olympus endoscope to inject contrast media into the biliary or pancreatic tract. They can also be used for retrieval of biliary or pancreatic stones.

F. SUMMARY INCLUDING CONCLUSIONS DRAWN FROM NON-CLINICAL TESTS

When compared to the predicate devices, these subject devices, Single Use 3-Lumen Balloon Catheter B-230Q-B / B-230Q-B do not incorporate any significant changes in the intended use, method of operation, materials, or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Aomori Olympus Corporation Ltd.
c/o Ms. Tina Steffanie-Oak
Associate Manager, RA/Clinical Monitor
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K033333
Trade/Device Name: Single Use 3-Lumen Balloon Catheter
Models B-230Q-A and B-230Q-B
Regulation Number: 21 CRR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: October 14, 2003
Received: October 17, 2003

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if known): _____

Device Name: B-230Q-A, B230Q-B (Single Use 3-Lumen Balloon Catheter)

Indications for Use:

These instruments have been designed to be used with Olympus endoscopes to inject contrast media into the biliary or pancreatic tract. They can also be used for retrieval of biliary or pancreatic stones.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033333